



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
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Kevin T. FOLEY *et al.*) Group Art Unit:
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Serial No.: 10/734,161) Examiner:
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CIP of U.S. Serial No. 10/359,996)
and U.S. Serial No. 09/815,693)
)
Filed: December 15, 2003)

For: METHODS FOR PERCUTANEOUS SURGERY

Mail Stop: Interference
Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

**REQUEST FOR DECLARATION OF INTERFERENCE
UNDER 37 C.F.R. §§ 1.607(a) and 1.604 AND REQUEST FOR EXAMINATION WITH
SPECIAL DISPATCH UNDER 37 C.F.R. § 1.607(b)**

Sir:

Applicants respectfully request, pursuant to 37 C.F.R. § 1.607, that the U.S. Patent and Trademark Office (USPTO) declare an interference between the above-identified U.S. Application No. 10/734,161 ("the present application") and U.S. Patent No. 6,530,926.

Applicants also respectfully request, pursuant to 37 C.F.R. § 1.604, that the USPTO declare that the aforementioned interference include U.S. Application No. 10/280,489.

Furthermore, pursuant to the provisions of 37 C.F.R. § 1.607(b), Applicants request that examination of the present application be conducted with special dispatch.

The information required by § 1.607(a) is set forth below in Section I under headings that correspond to the subsections of § 1.607(a). The information required by § 1.604(a) is set forth below in Section II under headings that correspond to the subsections of § 1.604(a).

I. RULE 607 REQUEST

(1) Identification of the Patent

The patent that includes the subject matter that interferes with subject matter claimed in the present application is U.S. Patent No. 6,530,926 (“the ‘926 patent”), issued on March 11, 2003, to Thomas W. Davison for a “Method of Securing Vertebrae.” The ‘926 patent issued from U.S. Application No. 09/630,077, filed August 1, 2000. Endius, Inc. is the assignee named on the face of the patent.

(2) Proposed Counts

Two proposed counts are set forth Appendix A. The counts are directed to methods for fixing vertebrae of a patient together. The first count includes the steps of inserting a cannula into the patient, inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra, inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra, and inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements. The second count includes all the steps of the first count and the additional step of expanding the cannula.

Count 1 is based upon issued claim 1 in the ‘926 patent. Count 2 is based upon issued claim 15 in the ‘926 patent. Each count corresponds to at least one claim in both the present application and the ‘926 patent. The counts define the common subject matter between the present application and the ‘926 patent (and U.S. Application No. 10/280,489, as will be discussed below in Section II). The inclusion of multiple counts in the same interference is appropriate where the counts are necessary to fully adjudicate the rights of the Applicants and the patent holder with regard to subject matter common to the two disclosures.

(3) Patent Claims Corresponding to the Proposed Counts

Claims 1-12 and 16-17 of the ‘926 patent correspond to proposed count 1. Claims 13-15 of the ‘926 patent correspond to proposed count 2.

Claim 1 of the ‘926 patent recites a method of fixing vertebrae of a patient together at a surgical site. Claim 1 of the ‘926 patent is essentially the same as proposed count 1, except that

proposed count 1 recites first, second and third fixation elements (*e.g.*, 2 pedicle screws and 1 plate), whereas claim 1 of the '926 patent recites first and second fasteners (*e.g.*, 2 pedicle screws) and a first fixation element (*e.g.*, a plate). This difference in claim terminology used to describe vertebral fixation elements, such as plates and screws, is insignificant to a person skilled in the art of vertebral fixation elements. Accordingly, claim 1 of the '926 patent does not define a patentably distinct invention with respect to count 1.¹

Independent claim 8 of the '926 patent is essentially the same as independent claim 1 and proposed count 1, except that independent claim 8 merely repeats the method with a second cannula at a second surgical site on the other side of the spine. Accordingly, claim 8 of the '926 patent does not define a patentably distinct invention with respect to count 1.

Independent claim 16 is essentially the same as independent claim 1 and proposed count 1, except that independent claim 16 recites the additional step of cutting away tissue at the surgical site using two cutting tubes, a method that was known for use in the relevant art prior to the filing date of the '926 patent. *See, e.g.*, U.S. Patent No. 5,364,395 at Figure 5. As such, claim 16 is not believed to define separately patentable subject matter, and should be designated as corresponding to proposed count 1.

Dependent claims 2-7, 9-12, and 17 of the '926 patent merely further define elements of independent claims 1, 8, or 16, or recite additional elements that were known for use in the relevant art prior to the filing date of the '926 patent. For example, claims 4-6 and 10-11 merely further define the recited fasteners and fixation elements as bone screws, plates, and rods, that were known in the art prior to the filing date of the '926 patent. *See, e.g.*, U.S. Patent No. 5,569,248 at col. 7, line 53 - col. 8, line 9 and Figures 1-3. Claims 3, 7 and 12 each recite conventional steps relating to preparation for and insertion of a fusion device between two vertebrae. Claims 2 and 9 relate to use of an endoscope. Claim 17 relates to use of a blood coagulation device, that was known in the art prior to the filing date of the '926 patent. *See, e.g.*, U.S. Patent No. 5,364,395 at col. 14, lines 4-9 and Figures 16-17. As such, these dependent

¹ Applicants note that they alternatively could present count 1 in disjunctive form as reciting claim 1 of the '926 patent "or" claim 1 of the present application. The Board of Appeals and Interferences specifically approved of this practice in *Hsing v. Myers*, 2 USPQ2d 1861, 1862 (BPAI 1987). The issue is the same however, as the difference in terminology is merely a semantic one, not reflecting a difference in inventive concept.

claims are not believed to define separately patentable subject matter with respect to proposed count 1, and therefore should be designated as corresponding to proposed count 1.

Claims 13-15 of the '926 patent correspond to proposed count 2. Independent claim 15 of the '926 patent recites a method of fixing vertebrae of a patient together at a surgical site. Claim 15 of the '926 patent is essentially the same as proposed count 2, except that (a) proposed count 2 recites first, second and third fixation elements (*e.g.*, 2 pedicle screws and 1 plate), whereas claim 15 of the '926 patent recites first and second fasteners (*e.g.*, 2 pedicle screws) and a first fixation element (*e.g.*, a plate); and (b) proposed count 2 recites "expanding the cannula," whereas claim 15 recites "expanding the first cannula at its end adjacent the first and second vertebrae." Neither of these differences renders claim 15 patentably distinct from proposed count 2. For example, as discussed above with respect to count 1, the difference in terminology used for vertebral fixation elements, *i.e.*, "fastener" vs. "fixation element," is insignificant. Furthermore, the recitation in proposed count 2 of "expanding the cannula" obviously contemplates a cannula that is expanded "at its end adjacent the first and second vertebrae," as recited in claim 15 of the '926 patent. Accordingly, claim 15 of the '926 patent should be designated as corresponding to proposed count 2.

Dependent claim 13 of the '926 patent is essentially the same as proposed count 2, except for the insignificant differences discussed above relating to (a) the terminology used to describe the fixation elements; (b) repeating the method with a second cannula on the other side of the spine; and (c) the recitation of expanding the cannula. Accordingly, dependent claim 13 is patentably indistinguishable from proposed count 2 and therefore should be designated as corresponding to proposed count 2.

Dependent claim 14 merely recites the additional step of "shifting the first and second cannulae in the body to position the first and second cannulae to desired locations in the body." This additional step of claim 14, given proposed count 2, is not believed to define separately patentable subject matter with respect to the subject matter of proposed count 2. Accordingly, claim 14 of the present application should be designated as corresponding to proposed count 2.

(4) Application Claims Corresponding to the Proposed Counts and Explanation of Correspondence to Counts

Count 1

Claims 1-6 of the present application correspond to proposed count 1.

Independent claim 1 of the present application corresponds exactly to proposed count 1. Dependent claims 2-4 of the present application merely recite steps that do not define separately patentable subject matter with respect to the subject matter of proposed count 1. For example, claim 2 relates to use of an endoscope, claim 3 recites various conventional steps relating to preparing for and installing a fusion device, and claim 4 recites the step of cutting away tissue at the surgical site using a cutting instrument. Because these steps do not patentably distinguish claims 2-4 from proposed count 1, claims 2-4 should be designated as corresponding to proposed count 1.

Independent claim 5 of the present application is the same as proposed count 1, except that it recites the additional steps of moving a fusion device through the cannula and inserting the fusion device between first and second vertebra of a patient. The use of fusion materials in connection with fixation elements was known in the art prior to Applicants' effective filing date. Accordingly, these additional steps in claim 5, given the subject matter of proposed count 1, are not believed to define separately patentable subject matter with respect to proposed count 1. Claim 5 of the present application should therefore be designated as corresponding to proposed count 1.

Dependent claim 6 of the present application merely recites the additional steps of inserting a tissue retractor into the cannula and shielding tissue at the surgical site. The use of a tissue retractor through a cannula was known in the relevant art prior to Applicants' effective filing date. Accordingly, these additional steps, given the subject matter of proposed count 1, are not believed to define separately patentable subject matter with respect to proposed count 1. Claim 6 of the present application should therefore be designated as corresponding to proposed count 1.

Count 2

Claims 7-8 of the present application correspond to proposed count 2. Independent claim 7 of the present application corresponds exactly to proposed count 2. Dependent claim 8 merely recites the step of shifting the cannula in the body to position the cannula at a desired location in the body. This additional step of claim 8, given the subject matter of proposed count 2, is not believed to define separately patentable subject matter with respect to the subject matter of

proposed count 2. Accordingly, claims 7-8 of the present application should be designated as corresponding to proposed count 2.

(5) Application of Terms to Application Disclosure

Applicants' claims 1-8 have been presented as corresponding to the proposed counts. Attached as Appendix B is a table showing at least a portion of the support for Applicants' claims within the disclosure of the present application. For the Examiner's convenience, the table also includes citations to parent applications of the present application, indicating an earlier effective filing date than the filing date of the present application.

(6) Explanation Under 35 U.S.C. § 135(b)

Claims 1-8 of the present application were presented on December 15, 2003, which is less than one year after March 11, 2003, the issue date of the '926 patent. Accordingly, no explanation under 37 C.F.R. § 1.607(a)(6) is required.

II. RULE 604 REQUEST

(1) Proposed Count and Applicants' Corresponding Claim

Applicants propose count 1 in Appendix A as the count that defines the common subject matter between the present application and U.S. Application No. 10/280,489 (hereinafter "the '489 application"). Proposed count 1 corresponds to at least one claim in both the present application and the '489 application.

As set forth above in Section I, independent claim 1 of the present application corresponds exactly to the proposed count. Claims 2-6 of the present application correspond substantially to proposed count 1.

(2) Identification of Other Application and Claim

The application that includes the subject matter that interferes with subject matter claimed in the present application is U.S. Application No. 10/280,489 (the '489 application), filed on October 25, 2002 and published April 17, 2003 as U.S. Publication No. 2003/0073998. Endius, Inc. is the assignee named on the face of the published patent application. Independent

claim 1 of the '489 application corresponds to proposed count 1. Dependent claims 2-9 and 14 of the '489 application also correspond to proposed count 1.

(3) Explanation of Why an Interference Should Be Declared

The present application and the '489 application each contain at least one claim that corresponds to proposed count 1 and is patentable to the respective Applicants, subject to a judgment in the interference.

As explained above in Section I, claim 1 of the present application corresponds exactly to proposed count 1. Claims 2-6 of the present application are patentably indistinguishable from proposed count 1, and therefore should be designated as correspond to proposed count 1.

Claim 1 of the '489 application is patentably indistinguishable from proposed count 1 and therefore corresponds to proposed count 1. More specifically, claim 1 of the '489 application is essentially the same as proposed count 1, except that (a) proposed count 1 recites first, second and third fixation elements (*e.g.*, 2 pedicle screws and 1 plate), whereas claim 1 of the '489 application recites first and second fasteners (*e.g.*, 2 pedicle screws) and a first fixation element (*e.g.*, a plate); and (b) claim 1 of the '489 application recites the additional steps of moving a fusion device through the cannula and inserting the fusion device between first and second vertebra of a patient.

However, with respect to (a), as discussed above for claim 1 of the '926 patent, the difference in claim terminology for the vertebral fixation elements, *i.e.*, "fastener" vs. "fixation element," is insignificant. With respect to (b), the use of fusion devices in connection with fixation elements was known in the art prior to the effective filing date of the '489 application. *See, e.g.*, U.S. Patent No. 5,569,248. Accordingly, these additional steps in claim 1 of the '489 application, given the subject matter of proposed count 1, do not define separately patentable subject matter with respect to proposed count 1. Accordingly, an interference should be declared between the present application and the '489 application.

Claims 2-9 and 14 of the '489 application merely further define elements of claim 1 or recite the addition of elements that were known for use in the relevant art prior to the filing date of the '489 application. As such, they are not believed to define separately patentable subject matter, and should be designated as corresponding to proposed count 1 along with claim 1 of the '489 application. For example, claims 2, 3, 7, 8, and 9 merely repeat one or more of the steps

already recited in claim 1 of the '489 application for additional fixation elements. With respect to claims 4-6 and 14, these claims merely recite the addition of elements, *e.g.*, the use of tissue retractors and allograft material, that were known for use in the relevant art prior to the filing date of the '489 application or are obvious variations thereof. *See, e.g.*, U.S. Patent No. 5,613,937 at col. 10, lines 30-35 and U.S. Patent No. 6,485,518 at col. 6, lines 33-47. *See also* the '489 application at ¶ 245 ("The implant 2110 is formed by harvesting allograft material from a femur, as is known in the art."). Accordingly, these claims are not patentably distinguishable from proposed count 1 and therefore should be designated as corresponding to proposed count 1.

As explained above in Section I, the table in Appendix B shows at least a portion of the support for Applicants' claims 1-6 within Applicants' specification.

Claims 1-6 of the present application were presented on December 15, 2003, which is less than one year after April 17, 2003, the publication date of the '489 application. Accordingly, Applicants have complied with 35 U.S.C. § 135(b).

CONCLUSION

In view of the foregoing, Applicants respectfully request that the U.S. Patent and Trademark Office declare an interference between the present application and the '926 patent and the '489 application. Furthermore, pursuant to 37 C.F.R. § 1.607(b), Applicants request that the examination be conducted with "special dispatch."

If the Examiner believes that prosecution or declaration of the interference might be advanced by discussing the application or the contents of this request with Applicants' counsel, in person or by telephone, the undersigned would welcome the opportunity to do so.

It is believed that no fees are due with this request. However, in the event any fees are due, the Director is hereby authorized to charge the undersigned's Deposit Account No. 50-0206.

Date: 1/29/04

Respectfully submitted,

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APPENDIX A
Proposed Counts

1. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:

inserting a cannula into the patient;

inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;

inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and

inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.

2. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:

inserting a cannula into the patient;

expanding the cannula;

inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;

inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and

inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.

APPENDIX B
Support in the Present Application

Applicant's Claims	Application Support
1. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:	"The insertion of vertebral fixation elements can also be accomplished through the devices." Present application ¶ 147; '044 patent at col. 15, lines 3-4.
inserting a cannula into the patient;	"Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented." Present application ¶ 147; '044 patent at col. 15, lines 7-9.
inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;	"The insertion of vertebral fixation elements can also be accomplished through the devices." Present application ¶ 147; '044 patent at col. 15, lines 3-4. "In one specific embodiment, the fixation element can be a bone screw. . . . The devices allow insertion of the bone screw into the vertebra to be conducted under direct vision." Present application ¶ 147-148; '044 patent at col. 15, lines 12-27.
inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and	"The insertion of vertebral fixation elements can also be accomplished through the devices." Present application ¶ 147; '044 patent at col. 15, lines 3-4. "In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula." Present application ¶ 18; '044 patent at col. 4, lines 12-15. "The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw." Present application ¶ 148; '044 patent at col. 15, lines 31-34. A pedicle screw is always used in combination with a second pedicle screw secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second pedicle screws.
inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.	"The insertion of vertebral fixation elements can also be accomplished through the devices." Present application ¶ 147; '044 patent at col.

	15, lines 3-4. "The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw." Present application ¶ 148; '044 patent at col. 15, lines 31-34. A pedicle screw is always used in combination with a second pedicle screw secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second pedicle screws.
2. The method of claim 1, further comprising the step of positioning an endoscope in the cannula to provide a view of the activity at the surgical site.	"An elongated viewing element 50 is mountable inside cannula 20 adjacent the working channel 25." Present application ¶ 85; '044 patent at col. 5, lines 51-52. "The viewing element 50 can be of a variety of types, including a rigid endoscope or a flexible and steerable scope." Present application ¶ 110; '044 patent at col. 11, lines 39-41.
3. The method of claim 1, further comprising the steps of: removing a disk from between the first and second vertebrae;	"Again under direct vision, the disc space can be prepared for implantation of fusion materials or a fusion device. Typically, this preparation includes preparing an opening in the disc annulus, and excising all or part of the disc nucleus through this opening." Present application ¶ 149; '044 patent at col. 15, lines 51-55.
cleaning the area of the surgical site;	"In addition, during a discectomy, aspiration of the excised tissue is preferred, and irrigation will frequently assist in rapid removal of this tissue." Present application ¶ 118; '044 patent at col. 13, lines 21-24.
positioning a fusion device between the first and second vertebrae by moving the fusion device through the cannula; and	"The devices can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material." Present application ¶ 149; '044 patent a col. 15, lines 35-37. "A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device and into the prepared bore at the subject disc space." Present application ¶ 150; '044 patent at col. 15, lines 57-61.
positioning bone graft tissue in and around the surgical site by moving bone graft tissue through the cannula.	"In some instances, graft material is simply placed within the prepared bore. This graft material can also be passed through the

	working channel cannula 20 into the disc space location. In other procedures, graft material or bone chips are positioned across posterior aspects of the spine. Again, this procedure can be conducted through the working channel cannula particularly given the capability of the cannula to be moved to different angles from a single incision site in the skin.” Present application ¶ 151; ‘044 patent at col. 16, lines 1-9.
4. The method of claim 1, further comprising the step of cutting away tissue at the surgical site using a cutting instrument.	“A tissue retractor and discectomy instruments can be simultaneously extended through the working channel. In that illustrated embodiment, the discectomy instruments could include a trephine for boring a hole through the disc annulus and a powered tissue cutter for excising the herniated disc nucleus.” Present application ¶ 146; ‘044 patent at col. 14, lines 41-46.
5. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:	“The insertion of vertebral fixation elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4.
inserting a cannula into the patient;	“Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented.” Present application ¶ 147; ‘044 patent at col. 15, lines 7-9.
moving a fusion device through the cannula and inserting the fusion device between first and second vertebrae of the patient;	“The devices can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.” Present application ¶ 149; ‘044 patent a col. 15, lines 35-37. “A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device and into the prepared bore at the subject disc space.” Present application ¶ 150; ‘044 patent at col. 15, lines 57-61.
inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;	“The insertion of vertebral fixation elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4. “In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct

	<p>vision through a single working channel cannula.” Present application ¶ 18; ‘044 patent at col. 4, lines 12-15. “In one specific embodiment, the fixation element can be a bone screw. . . . The devices allow insertion of the bone screw into the vertebra to be conducted under direct vision.” Present application ¶ 147-148; ‘044 patent at col. 15, lines 12-27.</p>
<p>inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and</p>	<p>“The insertion of vertebral fixation elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4. “The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” Present application ¶ 148; ‘044 patent at col. 15, lines 31-34. A pedicle screw is always used in combination with a second pedicle screw secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second pedicle screws.</p>
<p>inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.</p>	<p>“The insertion of vertebral insertion elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4. “The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” Present application ¶ 148; ‘044 patent at col. 15, lines 31-34. A pedicle screw is always used in combination with a second pedicle screw secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second pedicle screws.</p>
<p>6. The method of claim 7, further comprising the step of inserting a tissue retractor into the cannula and shielding tissue at the surgical site.</p>	<p>“Once the spinal nerve root is exposed, a retractor, such as the retractors shown in FIGS. 4-8, can be used to gently move and hold the nerve root outside the working space. In one important aspect of the two retractors 70, 100, the portion of the retractor passing through the working channel 25 generally conforms to the inner surface of the cannula 20 so that the working channel 25 is not disrupted by the</p>

	retractor tool.” Present application ¶ 121; ‘044 patent at col. 14, lines 8-14.
7. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:	“The insertion of vertebral fixation elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4.
inserting a cannula into the patient;	“Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented.” Present application ¶ 147; ‘044 patent at col. 15, lines 7-9.
expanding the cannula;	“In accordance with a further variation of the present invention, the cannula 20 can be replaced by a similar device that is capable of maintaining a large working channel 25. For example, the cannula 20 can be replaced by an expanding cannula or dilator apparatus. In one specific embodiment, the apparatus can be a spiral wound tube that is unwound or expanded to provide the working channel dimension.” Present application ¶ 95; U.S. Patent 5,902,231 at col. 9, lines 40-46.
inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;	“The insertion of vertebral fixation elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4. “In one specific embodiment, the fixation element can be a bone screw. . . . The devices allow insertion of the bone screw into the vertebra to be conducted under direct vision.” Present application ¶ 147-148; ‘044 patent at col. 15, lines 12-27.
inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra;	“The insertion of vertebral insertion elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4. “In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula.” Present application ¶ 18; ‘044 patent at col. 4, lines 12-15. “The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” Present application ¶ 148; ‘044 patent

	at col. 15, lines 31-34. A pedicle screw is always used in combination with a second pedicle screw secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second pedicle screws.
inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.	“The insertion of vertebral insertion elements can also be accomplished through the devices.” Present application ¶ 147; ‘044 patent at col. 15, lines 3-4. “The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.” Present application ¶ 148; ‘044 patent at col. 15, lines 31-34. A pedicle screw is always used in combination with a second pedicle screw secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second pedicle screws.
8. The method of claim 7, further comprising the step of shifting the cannula in the body to position the cannula at a desired location in the body.	“As necessary, the cannula 20 can be angled to allow a greater region of bone removal, which may be necessary to permit removal of a greater portion of bone.” Present application ¶ 120; ‘044 patent at col. 13, lines 54-56. “Again, this procedure can be conducted through the working channel cannula particularly given the capability of the cannula to be moved to different angles from a single incision site in the skin.” Present application ¶ 151; ‘044 patent at col. 16, lines 5-9.